REMARKS

Applicants request examination of the subject application in view of the following remarks.

Claims 6-62, drawn to methods and formulations for the treatment, repair or prevention of, or the modulation of inflammation associated with damage to connective tissue, are pending in the application, with claims 6, 7, 29, 33, 43, and 53 being independent.

In a prior Office Action Restriction Requirement mailed July 11, 2007 ("Initial Restriction"), claims 6-62 were restricted among various Groups and species. In a Response to the Initial Restriction filed August 10, 2007, Applicants elected Group I, claims 6-30, 33-41, 43-51, 53-61, drawn to a composition comprising avocado/soybean unsaponifiable and aminosugar, glycosaminoglycan, or related compounds. Applicants traversed the Initial Restriction's requirement to elect only one of Groups I and II for prosecution, for the reasons set forth in the Response filed August 10, 2007.

Restriction Among Species

An Office Action Restriction Requirement mailed October 18, 2007 ("Restriction Requirement") requires Applicants to elect one specific compound as aminosugars (such as any one of those listed in claim 12), and one specific compound of glycosaminoglycan (such as any one of those listed in claim 15). The aminosugars listed in claim 12 are "glucosamine hydrochloride, glucosamine sulfate, glucosamine phosphate, mannosamine and salts of N-acetylglucosamine." The glycosaminoglycans listed in claim 15 are "chondroitin, chondroitin salts, hyaluronic acid, pentosan polysulfate and mixtures thereof."

Interview Summary

On November 8, 2007, Applicants' representative, Thomas Bradshaw, spoke over the phone with Examiner Shengjun Wang concerning the aminosugar and glycosaminoglycan Species restrictions set forth in the Restriction Requirement. During the phone call, Examiner Wang stated that he would consider glucosamine and its salts together in the same Species for

prosecution, and that he would consider chondroitin and its salts together in the same Species for prosecution.

Election

In response to the Species restriction in the Restriction Requirement, and further to the Examiner's Interview with Applicants' representative, Applicants hereby provisionally elect for examination the aminosugars **glucosamine hydrochloride, glucosamine sulfate, and glucosamine phosphate**, and provisionally elect for examination the glycosaminoglycans **chondroitin, chondroitin salts, and mixtures thereof**. The elected compounds correspond to **claims 6-30, 33-41, 43-51, 53-61**.

Applicants submit that N-acetylglucosamine is a derivative of glucosamine that should be considered together in the same Species as glucosamine and its salts. Accordingly, Applicants traverse the aminosugar Species restriction to the extent that the Examiner refuses to consider N-acetylglucosamine in the same species as glucosamine and its salts.

As explained in the Abstract of an article by Talent et al. entitled "Pilot Study of Oral Polymeric N-acetyl-d-glucosamine as a Potential Treatment for Patients with Osteoarthritis," *Clinical Therapeutics*, Vol. 18, No. 6, 1996 ("the Talent article"), attached hereto as **Exhibit 1**, N-acetylglucosamine is a derivative of glucosamine. As further noted in the Abstract, N-acetylglucosamine, like glucosamine sulfate and other derivatives of glucosamine, has been shown to be effective in the treatment of patients with osteoarthritis. (Osteoarthritis is a type of inflammation associated with damage to connective tissue.) Furthermore, as indicated in an article by Simanek et al. entitled "The Efficacy of Glucosamine and Chondroitin Sulfate in the Treatment of Osteoarthritis: Are These Saccharides Drugs or Nutraceuticals?", Biomed. Papers 149(1), 51-56 (2005) ("the Simanek article", attached hereto as **Exhibit 2**, N-acetylglucosamine is "a metabolic product of GS [glucosamine sulfate]." The Simanek article, p. 53.

Due to the close metabolic relationship between glucosamine (and its salts) and N-acetylglucosamine, a derivative of glucosamine, and further due to the similarities in chemical

structure and function between these compounds, Applicants submit that it would not be a serious burden on the Examiner to examine N-acetylglucosamine together with glucosamine salts. Accordingly, Applicants believe that a search and examination of both Groups could be made without substantial burden and that restriction is therefore unwarranted. *See* MPEP §803. Applicants further note that at least six other patents claiming a glucosamine component comprising glucosamine salts and/or N-acetylglucosamine were examined without an Office Action restriction between glucosamine salts, on the one hand, and N-acetylglucosamine on the other. See, e.g., U.S. Patent Nos. 5,587,363, 6,255,295, 6,271,213, 6,451,771, 6,492,349, and 6,797,289. Applicants respectfully submit that, as in these six patents, glucosamine salts and N-acetylglucosamine should be examined together in the present application.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to Deposit Account No. 50-0740.

Favorable consideration of this application is respectfully requested.

Dated: November 19, 2007

Respectfully submitted,

By 

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